

# Kentucky Board of Pharmacy

125 Holmes St.  
Frankfort, KY 40601

## Inspection Report

### Pharmacy

Name: *Demo Manufacturer*

Permit No.: *MODEMO*

Address: *Test, Test, KY 40601*

Phone:

Fax:

Email: *bob@kentucky.gov*

### Inspection

Date: *06/10/2019*

Time In: *11:50 AM*

Time Out:

Type: *Routine*

Notes: *None*

### Pharmacist and Interns

**B. STEVEN HART**

License: *010819*

Status: *Active*

PIC: *Yes*

### Manufacturer Area

Alarm System Maintained: 201 KAR 2:320 Section 5 (2)(a) *Compliant*

Authorized Access Maintained: 201 KAR 2:320 Section 5 (2)(b) and (c) *Compliant*

Drug Storage Area: 201 KAR 2:320 Section 2 (4)(a) and Section 5 (1)(a) *Compliant*

Lighting (Interior and Exterior): 201 KAR 2:320 Section 2 (4)(a) and Section 5 (2)(b) *Compliant*

Quarantine Area for Outdated, Damaged or Opened: 201 KAR 2:320 Section 2 (4)(b) and Section 5 (1)(b) *Compliant*

Refrigeration/Freezer: 201 KAR 2:320 Section 2 (4)(a) *Compliant*

Sanitation: 201 KAR 2:320 Section 2 (4)(a) and Section 5(1)(a) *Compliant*

Suitable Size and Construction: 201 KAR 2:320 Section 5 (1)(a) *Compliant*

Ventilation/Temperature/Humidity: 201 KAR 2:320 Section 2 (4)(a) *Compliant*

Defined Production Area: 201 KAR 2:105 Section 4 (1)(a) *Compliant*

### General

Controlled Drugs Secured: 201 KAR 2:320 Section 2(4)(d) and Section 5(4)(a), and 21 CFR 1301.72 *Compliant*

General (*continued*)

|   |                  |
|---|------------------|
| Customer Verification: KRS 315.400(18)  | <i>Compliant</i> |
| Drug Loss/Theft Records Maintained: 201 KAR 2:320 Section 2(4)(d) and Section 5(4)(a), and 21 CFR 1301.76 | <i>Compliant</i> |
| Personnel Training Program: 201 KAR 2:320 Section 5 (2)(d)  | <i>Compliant</i> |
| Product and Process Controls: 201 KAR 2:320 Section 5 (7)   | <i>Compliant</i> |
| Receipt and Distribution Transaction Records for 2 Years: 201 KAR 2:320 Section 5 (3)(a)                  | <i>Compliant</i> |
| Records Maintained and Complete: 201 KAR 2:320 Section 5 (3)(b)   | <i>Compliant</i> |
| Records Readily Retrievable: 201 KAR 2:320 Section 5 (3)(b)   | <i>Compliant</i> |
| Stock Rotation of Pharmaceuticals: 201 KAR 2:320 Section 5 (7)(b)   | <i>Compliant</i> |
| Quarterly PIC Inspection Complete: 201 KAR 2:105 Section 5<br>Date: 06/10/2019                            | <i>Compliant</i> |
| Finished Product Appropriately Labeled: KRS 217.065   | <i>Compliant</i> |
| Label Security and Control: 21 CFR 211.125  | <i>Compliant</i> |
| Batch Records Maintained: 201 KAR 2:105 Section 4 (3)(a) and KRS 217.155(1)(c)                            | <i>Compliant</i> |
| Established Quality Assurance Process: KRS 217.055  | <i>Compliant</i> |
| Established Returns Process: KRS 315.404(4)   | <i>Compliant</i> |
| Employees Screened Per DEA Requirements: 21 CFR 1301.90   | <i>Compliant</i> |
| Biennial Controlled Substance Inventory: KRS 218A. 200(7)(a)<br>Date: 06/10/2019                          | <i>Compliant</i> |
| Most Recent FDA Inspection<br>Date: 06/10/2019  | <i>Compliant</i> |

## Written Policies and Procedures

|  |                  |
|--|------------------|
| Distressed Drugs: 201 KAR 2:320 Section 5 (5)                                | <i>Compliant</i> |
| Correcting Errors/Inaccuracies in Inventories: 201 KAR 2:320 Section 5(4)(b) | <i>Compliant</i> |
| Outdated Pharmaceuticals: 201 KAR 2:320 Section 5(4)(c)                      | <i>Compliant</i> |
| Shipping/Receiving of Stock: 201 KAR 2:320 Section 5(4)(d)                   | <i>Compliant</i> |

Written Policies and Procedures (*continued*)

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Security/Diversion: 201 KAR 2:320 Section 5(2)(c) and (4)(a)

*Compliant*

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Recalled Drugs: 201 KAR 2:320 Section 5 (6)

*Compliant*

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Crisis/Emergency Policy: 201 KAR 2:320 Section 5(4)(a)

*Compliant*

## Inspector's Signature

I have completed this inspection in accordance with the statutes and administrative codes.

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Inspector: *Katie Busroe*

## Pharmacist's Signature

I have read and understand the statutes and administrative codes. I acknowledge that the items noted in this report have been discussed with me. I understand that if I disagree with any of the deficiencies cited, that I have the right to refute them on this report or on another form that I choose to send to the department.

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Pharmacist: